

## REMARKS

### I. PROSECUTION HISTORY

Applicants elected claims 26, 30, and 31 (Group VII) with traverse in response to a restriction requirement mailed May 17, 2002, in which the Office alleged that the claims as filed were directed to twelve distinct inventions. In an action mailed December 3, 2002, the Office maintained the restriction and rejected the elected claims 26, 30 and 31 on various grounds, and additionally presented objections relating to priority and the previously submitted Information Disclosure Statement. In a final action mailed August 27, 2003, the Office rejected claims 26, 30, 31, 38 and 39 on various grounds, and withdrew claims 40-43 for allegedly being directed to a non-elected invention, claims 1-14, 27-29, and 32-37 having been earlier withdrawn.

The claims are not being amended with this response. However, the claims are provided above for the convenience of the Office.

### II. THE RESTRICTION OF THE CLAIMS SHOULD BE REMOVED

On page 2 of the Office action, the Office maintained the earlier restriction on the basis of the Vicari reference. The applicants respectfully traverse. Contrary to the Office action's description, applicants did not state that "TECK" was a murine "counterpart" to human MDC. Quite the contrary, applicants stated that "TECK" was not a murine "counterpart" to human MDC.

### III. CLAIMS 40-43 ARE DIRECTED TO THE ELECTED INVENTION, AND SHOULD BE ACCORDINGLY CONSIDERED

On page 2 of the Office action, the Office alleged that claims 40-43 were directed to a non-elected invention. The applicants respectfully traverse.

As to claims 40 and 41, they are directed to MDC antagonists that may be used to palliate allergic reactions. On page 7 of the amendment filed June 3, 2003, applicants explained the reasoning behind the amendment to claim 30 and the addition of claims 40 and 41 as follows: "The various specific fragments and analogs disclosed in the present application provide sufficient support for the original 'fragment or analog' language. However, in order to expedite prosecution, claim 30 has been amended so as to omit the phrase '(a) a polypeptide fragment or analog of a vertebrate MDC that inhibits MDC activation.' New claims 40 and 41 define specific antagonists by structure." Because claim 30 is within the elected group, claims 40 and 41 must necessarily also be within the elected

group. Accordingly, the withdrawal of claims 40 and 41 was improper, and the applicants request that they now be considered.

As to claims 42 and 43, they are directly analogous to claims 26 and 30. In applicants' September 17, 2002 response to the restriction requirement of May 17, 2002, applicants elected (with traverse) Group VII claims drawn to a method of palliating an allergic reaction in a mammalian subject using "an MDC antagonist compound or TARC antagonist compound." Before the amendment filed June 3, 2003, claim 26 was directed to a method of palliating an allergic reaction comprising the use of either "an MDC antagonist compound or *TARC antagonist compound*." (emphasis added; see also Appendix A of the June 3rd amendment) The said amendment split claim 26 into two separate claims: claim 26 (directed to an MDC antagonist compound) and claim 42 (directed to a TARC antagonist compound). Because claim 26 as elected was directed to both MDC antagonist compounds and TARC antagonist compounds, claim 42 must necessarily also be within the elected group. A similar argument applies to claim 43, *i.e.*, because claim 30 is in the elected group, claim 43 must also be. Accordingly, the withdrawal of claims 42 and 43 was improper, and the applicants request that they now be considered.

The subject matter currently claimed in claims 26, 30, 31 and 38-43 is within the scope of the claims originally elected (Group VII). At the time of the restriction requirement, the Office made no indication of any kind of restriction requirement within Group VII, *e.g.*, a species election. If the Office now feels that a species or other restriction is required, the Office should so indicate, remove finality, and allow applicants to make an election. "Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct." *See* M.P.E.P. § 806. The Office has provided neither argument nor evidence that claims 40-43 are patentably distinct or independent from claims 26, 30, 31, 38 and 39. If the Office does not feel a further restriction is necessary, the applicants respectfully request that claims 40-43 be considered along with claims 26, 30, 31, 38 and 39.

**IV. THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN, BECAUSE THE SPECIFICATION IS ENABLING AS FILED**

On page 3 of the Office action, the Office stated that claims 26 and 30 remained rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicants respectfully traverse, but also interpret the Office action to mean that the rejection no longer applies to claim 31, and also does not apply to any of the other claims.

The Office action alleged that the published data supplied with the previous response did not provide support that other polypeptides besides antibodies against MDC are able to suppress an allergic reaction. This allegation is improper on a number of different levels including, but not limited to the following:

First, the Kawasaki article (Exhibit E in the previous response) demonstrates successful treatment using anti-TARC antibodies, thus showing that not only anti-MDC antibodies, but also anti-TARC antibodies, may be used successfully.

Second, the elected claims (i.e., claims 26, 30, 31, 38-43) ***are directed to methods of using antagonists, not the antagonists themselves; and the applicants are not obligated to describe every possible antagonist*** that could be used with claimed methods in order to enable one skilled in the art. The published data of all three exhibits, as well as the present specification, demonstrate more than a sufficient number of examples of both MDC antagonist compounds and TARC antagonist compounds, and how they may be used to palliate an allergic reaction.

The presence or absence of an example is not determinative on the issue of enablement, and an applicant need not describe all actual embodiments in order to have an enabling disclosure. See M.P.E.P. § 2164.02. Example 33, beginning on page 107 of the specification demonstrates how MDC antagonist compounds and TARC antagonist compounds can be tested and used to palliate an allergic reaction. Antibodies 252Y and 252Z, described in Examples 18 may be used according to the teachings of Example 33, as can the antibodies discussed in the published studies (Exhibits C-E of Applicants' June 3, 2003 response), as well as any other MDC or TARC antagonist compound. Examples 13, 18 and 26 also supply methods that can be used or adapted to identify and test other suitable antagonists without undue experimentation in a manner consistent with *In re Wands*. The examples of antagonists disclosed in the specification amply demonstrate the principle that an MDC antagonist compound or a TARC antagonist compound may be used to palliate an allergic reaction.

Accordingly, the rejection of claims 26 and 30 under 35 U.S.C. § 112, first paragraph, should be withdrawn. Similarly, any rejection of claim 31 or claims 38-43 under 35 U.S.C. § 112, first paragraph, would be improper.

### SUMMARY

The applicants respectfully request prompt reconsideration of the pending claims. The claims are believed to be in condition for allowance in view of the foregoing amendments and remarks. Withdrawal of the rejections and allowance of the claims are respectfully solicited.

No fees are believed due. Nevertheless, the Commissioner is hereby authorized to charge any fees due with this response to Deposit Account No. 13-2855.

The examiner is invited to contact the undersigned at the telephone number listed below in order to discuss any remaining issues or matters of form that will move this case to allowance.

Respectfully submitted,

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By



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